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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,472	07/27/2001	Leland F. Wilson	9050-0013.23	4971

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EXAMINER

CRIARES, THEODORE J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 10/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/919,472

Applicant(s)

WILSON ET AL.

Examiner

Theodore J. Criares

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **CLAIMS 1-54 ARE PRESENTED FOR EXAMINATION**

### **DETAILED ACTION**

Applicant's arguments filed April 12, 2003 have been fully considered but they are not persuasive.

The applicants arguments are misdirected since pursuant to MPEP 2164 there is sufficient reasons of record to doubt the objective truth of the statements contained therein which must be relied on for enabling support. The applicants' claims are drawn to the use of androgenic agents to enhance sexual desire and responsiveness in a female individual.

This is the problem to be solved. However, the examiner has established that the prior art as illustrated by the Hutchinson et al and Mathew et al references that an androgenic agent, testosterone, is unlikely to have a place in the treatment of sexually unresponsive females.

The applicants' remarks also illustrate the state of the art is doubtful and unpredicable. For example applicants admit that there is a problem to be solved to enhance sexual desire and response in a female. At page 11, last paragraph of number 1 it is admitted that as of the date of the filing of the subject application, the problem was still being addressed. The fact that a protocol of Example 9 is taught does not prove the fact that the problem and doubt as raised by the cited references is solved. At most it establishes that further undue experimentation is needed to determine if the problem is solved with the active agents claimed and taught by applicants.

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The prior art as set forth by the examiner is sufficient reason that a doubt exists as to the agents claimed by applicant will enhance sexual desire and responsiveness in a female individual.

There is sufficient reason for doubt how to use applicants' invention See In re Marzocchi. 439 F2. 220, 169 USPQ 367 (CCPA 1971). Therefore, the burden is on the applicants to establish that androgenic agents are useful in enhancing the sexual desire and responsiveness in a female individual.

The previous Office Action is deemed proper and repeated herein as follows :

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the enhancing sexual desire and responsiveness in a female individual by administering androgenic agent in a chronic dosage regimen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors**

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have been considered with regard to the instant claims, with the most relevant factors discussed below.

***Nature of the Invention:*** All of the rejected claims are drawn to enhancing sexual desire and responsiveness in a female individual by administering androgenic agent in a chronic dosage regimen. The nature of the invention is extremely complex in that it requires that female sexual desires be enhanced. The biological pathways involved in such enhancement is complex since it involves various hormones. Hutchinson et al. (BM) evidence this fact at pages 114s and 115s since they report that "(N)o evidence suggests that exogenous androgens play any role in the treatment of sexual dysfunction in the reproductive-aged women." Further, the complexity of the invention can be seen in Mathews et al (BN)reference which states in the Abstract that testosterone (an androgenic agent) is unlikely to have a useful place in the treatment of sexually unresponsive women.

**Breath of the Claims:** The complex of nature of the claims is greatly exacerbated by breadth of the claims since they encompass a multitude of androgenic agents.

**Guidance of the Specification:** The guidance given by the specification as to how one would administer the claimed compounds to a subject in order to actually enhance sexual desire in a female is limited. The examples only relate to a method by which the sexual desire can be determined but not the results of such tests. In other words the specification outlines a protocol but no results.

**Working Examples:** All of the working examples provided by the specification are directed toward the protocol.

**State of the Art:** The state of the art is that androgenic agents will not enhance sexual desire and the applicant has not provided data that provides the Examiner that all androgenic agents or reasonable representation thereof will enhance female sexual desires.

**Predictability of the Art:** The lack of significant guidance from the specification or prior art with regard to the actual enhancement of sexual desire in a female with the claimed compounds makes practicing the claimed invention unpredictable.

**The amount of Experimentation Necessary:** In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test. The combination in the model system to determine whether or not the agents are effective for enhancing sexual desire in a female If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding the ability of androgenic agents to enhance female sexual desire with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of

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the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding enhancing sexual desire in a female with any androgenic agent, the entire, unpredictable process would have to be repeated until successful.

Therefore, it would require undue, unpredictable experimentation to practice the claimed invention.

None of the claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

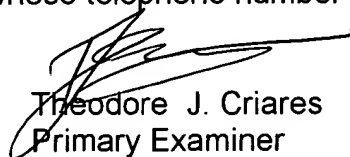
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.



Theodore J. Criares  
Primary Examiner  
Art Unit 1617

10/22/03

tjc